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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,043	12/04/2000	M. Suzanne Bradshaw	4167-4000	4527

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Morgan & Finnegan LLP
345 Park Avenue
New York, NY 10154

EXAMINER
QIAN, CELINE X

ART UNIT	PAPER NUMBER
1636	14

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/729,043	BRADSHAW ET AL.	
	Examin r	Art Unit	
	Celine X Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-17 and 20-37* is/are pending in the application.

4a) Of the above claim(s) *14-17 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 14-17 and 20-37 are pending in the application. Claims 14-17 and 20 are withdrawn from consideration for being directed to non-elected subject matter. Claims 21-37 are currently under examination.

This Office Action is in response to the Amendment filed on 5/19/03.

Response to Amendment

The rejection of claims 18 and 19 under 35 U.S.C.101 is moot in light of Applicants' cancellation of the claims.

The rejection of claims 18 and 19 under 35 U.S.C.112 1st paragraph is moot in light of Applicants' cancellation of the claims.

The rejection of claims 18 and 19 under 35 U.S.C.112 2nd paragraph is moot in light of Applicants' cancellation of the claims.

The newly added claims 21-26 and 29-31 are rejected under 35 U.S.C.112 1st paragraph for reasons set forth of the record mailed on 12/17/02 and further discussed below.

Claims 21-28 and 35-37 are rejected under 35 U.S.C.112 2nd paragraph for reasons discussed below.

Claims 27, 28 and 34-37 are rejected under 35 U.S.C.102 (b) for reasons discussed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a transgenic non-human mammal having integrated into its genome a defined segment of DNA as claimed by microinjection, does not reasonably provide enablement for such method wherein the DNA is introduced to the non-human mammal by other method such as chemical transfection, electroporation, or chimera production. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The claims are drawn to a method of producing transgenic non-human mammal comprising introducing a defined segment of DNA into the genome of the non-human mammal by integrating defined segment of DNA into the genome of a mammal. The claimed method is only enabled for producing a transgenic non-human mammal in which the step of integrating defined segment DNA into a mammalian genome is accomplished by microinjection of the defined segment of DNA into pro-nucleus of a mammalian embryo. The claimed method of making a transgenic mammal also reads on somatic cell gene transfer *in vivo*, which does not necessarily result in germline transmission of the genetic modification. The method is not enabled for making a chimeric non-human mammal. Moreover, the claimed method is not enabled wherein the defined segment of DNA is introduced to genome of the mammal by chemical transfection, electroporation or chimera production. The state of art at the time of filing only supports the enablement for generating non-human transgenic mammal by pro-nuclear injection. Other types of method for integrating a transgene into the genome of a mammal such as chemical transfection or electroporation is only enabled for introducing

transgene into mouse ES cells, and subsequently introduce the ES cell into a blastocyst and further development of said blastocyst into a chimeric mouse, wherein mating of the chimeric mouse finally produces the transgenic mouse. The specification does not teach a method of integrating DNA into the genome of any non-human mammal by methods such as chemical transfection or electroporation. Therefore, without teaching from the specification, a skilled artisan would have to engage in undue experimentation to practice the method to its full scope. As such, the claimed method is only enabled to the scope discussed above.

Claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a transgenic mouse embryo having integrated into its genome a defined segment of DNA as claimed by homologous recombination in mouse ES cells, does not reasonably provide enablement for a method of producing any other transgenic non-human embryo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The claimed method is not enabled for producing non-human transgenic embryos having integrated in its genome a defined segment of DNA except a transgenic mouse embryo. The claimed method relies on integrating defined segment of DNA by homologous recombination in embryonic stem cells. As discussed in the previous office action mailed on 12/17/02, the art teaches that embryonic stem cell is only available in mouse at the time of filing. The specification does not provide any guidance in isolating ES cells from other non-human

mammal. Therefore, the claimed method is only enabled for generating a mouse transgenic embryo.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to produce a transgenic, non-human mammal. The claimed method lack steps for introducing the DNA into a non-human embryo by microinjection, develop the embryo into a chimeric non-human animal, and further breeding said mouse to generate a transgenic non-human animal.

Claims 29-37 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: How to generate a transgenic embryo from a chimeric embryo. The product generated from steps a) to i) is a chimeric embryo having the defined segment of DNA. Additional method steps is required for developing the chimeric embryo to a chimeric mouse and further breeding the chimeric mouse to obtain a transgenic mouse embryo.

Regarding claim 26, the recitation of "chimera production" renders the claim indefinite because it is unclear where this step should fit into the method steps of the parent claim 21.

Claim 21 recites "integrating the defined segment of DNA into genome of a mammal" as the last step of generating the transgenic mammal. It is unclear in which step the chimera is produced, and how this chimera is developed into a transgenic mammal.

Claim 28 recites the limitation "the transgenic non-human mammal of claim 26" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 26 is drawn to a method of producing a transgenic non-human mammal.

Claims 35-37 recite the limitation "transgenic mouse" in line 1. There is insufficient antecedent basis for this limitation in the claim because the parent claim, 29 or 35, only recites a transgenic, non-human embryo, not a transgenic mouse.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 28, 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Strauss et al. (1994, JBC, Vol.269, No.7, pp.4968-4973).

Claims 27, 28, 34-37 are product by process claims which read on the product, in the present instance, a transgenic non-human mammal or a cell from said mammal.

Strauss et al. disclose a transgenic mouse carrying a cosmid insert containing the CG-beta genes (see abstract). Therefore, Strauss et al. disclose the instant claimed inventions. Absent evidence to the contrary, the method by which the transgenic non-human mammal is made does

not impart upon said non-human mammal or a cell obtained from it a patentable distinction from another such transgenic mammal or cell, as taught by Strauss et al., for example.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
August 8, 2003

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER